REMARKS

Reconsideration is requested.

Claims 8 and 12 are pending.

Claim 8 has been allowed.

Claim 12 has been further revised, without prejudice. Support for the amendment may be found, for example, in originally-filed claim 2 and throughout the specification.

The isolated bacterial strain of independent claim 12 is supported by an adequate written description. One of ordinary skill in the art will appreciate that the applicants were in possession of the claimed invention at the time the application was filed.

The rejection of claim 12 under 35 U.S.C. § 112, first paragraph, is traversed. Reconsideration and withdrawal of the rejection are requested in view of the above and the following.

Independent claim 12 defines an isolated bacterial strain which is an *Exiguobacterium lactigenes* strain, the isolated bacterial strain comprising a 16S rRNA sequence of SEQ ID NO:1, wherein the genomic DNA of said isolated bacterial strain is capable of hybridizing with at least 70% of the genomic DNA of the strain deposited[1] on December 5, 2002, under the No. I-2962, with the Collection Nationale de Cultures de Microorganismes (C.N.C.M.), the isolated bacterial strain being thermoresistant,

[1] See for example, page 2, lines 3-5 of the specification and originally-filed claim 2.

saccharolytic and amylolytic and/or capable of producing L(+) lactate[2], and having growth properties at temperatures of 40 to 50°C, at a pH of 5.4 to 9.15, with an optimum for growth at 45°C, at a pH of approximately 7, and a guanine plus cytosine content of its DNA of approximately 50 mol%. The claimed subject matter is described in the specification and originally-filed claims, as demonstrated above.

As described in MPEP § 2163, there is a

> "strong presumption that an adequate written description of the claimed invention is present when the application is filed. In re Wertheim, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976) ("we are of the opinion that the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims"). "

As the appealed independent claim 12 is a combination of originally-filed claims 1, 2, 3, 4, 5 and 6 (which depended from claim 1), there is a "strong presumption" that the appealed independent claim 12 is supported by an adequate written description. The Examiner has failed to overcome this "strong presumption" and the Section 112, first paragraph "written description", rejection should be reversed.

The Examiner has asserted that the specification allegedly fails to describe more than the specifically deposited strain which is the subject of allowed independent claim 8.

As explained however in Capon v. Eshhar, 76 USPQ2d 1078, 1084 (Fed. Cir. 2005),

> The "written description" requirement implements the principle that a patent must describe the technology that is sought to be

[2] See for example, page 5, lines 1-5 of the specification and originally-filed claim 4.

> patented; the requirement serves both to satisfy the inventor's obligation to disclose the technologic knowledge upon which the patent is based, and to demonstrate that the patentee was in possession of the invention that is claimed. *See Enzo Biochem*, 296 F.3d at 1330 (the written description requirement "is the quid pro quo of the patent system; the public must receive meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time"); *Reiffin v. Microsoft Corp.*, 214 F.3d 1342, 1345-46 (Fed. Cir. 2000) (the purpose of the written description requirement "is to ensure that the scope of the right to exclude . . . does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification"); *In re Barker*, 559 F.2d 588, 592 n.4 (C.C.P.A. 1977) (the goal of the written description requirement is "to clearly convey the information that an applicant has invented the subject matter which is claimed"). The written description requirement thus satisfies the policy premises of the law, whereby the inventor's technical/scientific advance is added to the body of knowledge, as consideration for the grant of patent exclusivity.
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> The descriptive text needed to meet these requirements varies with the nature and scope of the invention at issue, and with the scientific and technologic knowledge already in existence. The law must be applied to each invention that enters the patent process, for each patented advance is novel in relation to the state of the science. Since the law is applied to each invention in view of the state of relevant knowledge, its application will vary with differences in the state of knowledge in the field and differences in the predictability of the science.

Further, the Court of Appeals for the Federal Circuit has explained as follows in In re Kenneth Alonso (2008-1079 Fed. Cir. October 30, 2008) with regard to the written description requirement in the case of a criteria for a claim defining a genus of antibodies.

> The written description requirement of 35 U.S.C. § 112, ¶ 1, is straightforward: "The specification shall contain a written description of the invention … ." To satisfy this requirement, the specification must describe the invention in sufficient detail so "that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought.

> The requirement "serves a teaching function, as a 'quid pro quo' in which the public is given 'meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time."
>
> The requirement is rigorous, but not exhaustive: "[I]t is unnecessary to spell out every detail of the invention in the specification; only enough must be included to convince a person of skill in the art that the inventor possessed the invention. LizardTech, 424 F.3d at 1345.

The applicants submit that the determination of what is needed to support generic claims to biological subject matter depends on a variety of factors, such as the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, the predictability of the aspect at issue, and other considerations appropriate to the subject matter.[3] For example, it is unnecessary for the specification to provide a description of proteins which are already known in the prior art.[4].

The applicants have provided evidence[5] in this regard to demonstrate that the recitation of 70% hybridization of claim 12 is commonly accepted by scientists and those of ordinary skill in the art as a description of related strains. One of ordinary skill in the art will appreciate that this characteristic of the claimed strains along with the additionally recited characteristics of the claimed invention are sufficient to conclude that the applicants were in possession of the claimed invention at the filing date of the application.

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[3] See Capon 76 USPQ.2d 1085.
[4] See Capon 76 USPQ.2d 1087.

The Examiner acknowledges that Wayne et al demonstrates that strains belonging to the claimed species will be expected to exist, presumably as defined by the criteria confirmed by Wayne et al.[6] The Examiner's rejection appears to be based only on an allegation that the rejected independent claim 12 is too broad.[7] The Examiner appears to believe that further working examples or further strains within the claimed species would be required to demonstrate possession of the claimed invention.

No such further isolated strains or working example however should be required to describe the claimed invention. The Examiner has acknowledged that the applicants have demonstrated and/or that one of ordinary skill will appreciate that further strains will exist within the claimed species, and that such further strains will have the characteristics of and be described by the elements of the rejected claim. The Examiner has failed to indicate or describe or detail what further may be required to describe the claimed invention or to demonstrate that the applicants were in possession of the claimed invention at the time the application was filed.

In Enzo Biochem v. Gen-Probe, Inc., 63 USPQ2d 1609, 1613 (Fed. Cir. 2002), the court stated that the written description requirement would be met for all of the

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[5] See Wayne et al "Report of the Ad Hoc Committee on Reconciliation of Approaches to Bacterial Systematics" International Journal of Systematic Bacteriology, Oct. 1987, vol. 37, No. 4, pages 463-464 (of record).

[6] "Applicant argued that the percentage of 70% homology or DNA-DNA hybridization or relatedness would be acceptable in the art, referring Wayne et al. It is understood that the percentage cited by Wayne et al. is a criteria for a phylogenetic definition of species, and it is understood that certainly there are strains belong to the same species of Exiguobacterium lactigenes. Considering the broadest scope of the instant claim and a single species (strain) disclosed in the specification (e.g. I-2962), it is not considered that the specification provides the written description that the inventors possess entire strains of a species of Exiguobacterium lactigenes as claimed." See page 5 of the Office Action dated January 12, 2010 (emphasis added).

[7] Id.

claims of the patent at issue if the functional characteristic of the claimed invention was coupled with a disclosed correlation between that function and a structure that is sufficiently known or disclosed. The structure of the claimed invention, such as is described by the 70% hybridization requirement, will be appreciated by one of ordinary skill to be related to the additionally recited functional characteristics of the claimed strains, as evidenced by, for example, Wayne et al

Finally, the applicants note that the Federal Circuit has stated that as long as an applicant has disclosed a "fully characterized antigen," either by its structure, formula, chemical name, or physical properties, or by depositing the protein in a public depository, the applicant can then claim an antibody by its binding affinity to that described antigen.[8]

In the present application, the strains of the rejected claim are characterized by their relationship to the fully characterized and deposited strain recited in the claim.

As explained by the Federal Circuit in In re Kenneth Alonso[9]

> A genus can be described by disclosing: (1) a representative number of species in that genus; or (2) its "relevant identifying characteristics," such as "complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics."

In the present specification, the applicants have described and deposited a representative species, described representative sequence of the 16s rRNA required by the claimed strains and described a combination of physical and chemical properties as

[8] See Noelle v. Lederman, 69 USPQ2d 1508, 1514 (Fed. Cir. 2004).
[9] 88 USPQ2d 1849, 1852 (Fed. Cir. 2008).

well as functional characteristics of the claimed strains. One of ordinary skill will appreciate that the applicants were in possession of the claimed invention at the time the application was filed.

The written description requirement is satisfied by the applicants conveyance with reasonable clarity to those skilled in the art that as of the filing date the applicants were in possession of the claimed invention.[10] An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention.[11] Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention.[12] The applicants are not required to show a reduction to practice or exemplification of every aspect of the claimed invention to demonstrate an adequate written description, as appears to be required by the present Examiner.

The claims are supported by an adequate written description. Basis for the rejected claim is found throughout the specification and originally-filed claims such that there is a strong presumption that an adequate written description of the claimed

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[10] See Ralston Purina Co. v. Far-Mar-Co., Inc., 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting In re Kaslow, 217 USPQ 1089, 1096 (Fed. Cir. 1983)).

[11] See Lockwood v. American Airlines, Inc., 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

[12] See, for example, Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); Regents of the University of California v. Eli Lilly, 43 USPQ2d 1398, 1406 (Fed. Cir.

invention was present in the specification as filed. The Examiner has failed to rebut this presumption. The specification is not required to exemplify or reduce to practice every aspect or embodiment of the claimed invention. One of ordinary skill in the art will appreciate that the applicants were in possession of the claimed invention at the time the application was filed.

Withdrawal of the Section 112, first paragraph "written decryption", rejection of claim 12 is requested.

The claims are submitted to be in condition for allowance and a Notice to that effect is requested. The Examiner is requested to contact the undersigned, preferably by telephone, in the event anything further is required in this regard.

Respectfully submitted,

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1997); Amgen, Inc. v. Chugai Pharmaceutical, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it").